1. **What StructoKabiven Perifer is and what it is used for**

StructoKabiven Perifer is an emulsion for infusion given into your blood by a drip (intravenous infusion). The product contains amino acids (components used to build proteins), glucose, fat and salts in a plastic bag.

It is used as part of a balanced intravenous diet, together with salts, trace elements and vitamins which together provide your complete nutritional needs.

2. **Before you use StructoKabiven Perifer**

**Do not use StructoKabiven Perifer if you:**
- are allergic (hypersensitive) to any of the ingredients of StructoKabiven Perifer.
- are allergic to egg, peanut or soya. The product contains soyabean oil
- have too much fat in the blood (hyperlipidemia)
- have serious liver disease
- have blood clotting problems (coagulation disorders or haemophagocytotic syndrome)
- your body has problems using amino acids
- have serious kidney disease without access to dialysis
- are in acute shock
- have too much sugar in your blood (hyperglycaemia)
- have high blood (serum) levels of the salts (electrolytes) included in StructoKabiven Perifer
- have fluid in the lungs (acute pulmonary oedema)
- have too much body fluid (hyperhydrated)
- have heart failure that is not treated
- don’t have enough body fluid (hypotonic dehydration).
- are in an unstable condition, such as after serious trauma, uncontrolled diabetes, acute heart attack, metabolic acidosis (a disturbance resulting in too much acid in the blood), serious infection (severe sepsis) and coma

**Take special care with StructoKabiven Perifer**
Tell your doctor if you have:
- kidney problems
- diabetes mellitus
- pancreatitis (inflammation of the pancreas)
- liver problems
- hypothyroidism (thyroid problems)
- sepsis (serious infection)

StructoKabiven Perifer is not meant for newborn babies or children younger than 2 years of age. At the moment, there is no experience of the use of StructoKabiven Perifer in children from 2 to 11 years old.

Your doctor may want to do regular blood tests to make sure your body is using StructoKabiven Perifer correctly.

**Taking other medicines**
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, even without a prescription.
Inform your doctor if you are taking
- a drug known as heparin which is used to prevent the formation and aid in the dispersion of blood clots
- anticoagulating agents (coumarin derivates) as Vitamin K₁, which is contained in soybean oil, could affect the blood clotting ability
- insulin for the treatment of diabetes

**Pregnancy and breast-feeding**
You should tell your doctor if you are pregnant (or think that you might be) likely to become pregnant or are breast-feeding.

StructoKabiven Perifer should be used during pregnancy only after special consideration.
Women treated with StructoKabiven Perifer should not breastfeed.

Ask your doctor or pharmacist for advice before taking any medicine.

**Driving and using machines**
No effects on the ability to drive and operate machines are to be expected.

**Important information about one of the ingredients of StructoKabiven Perifer**
This medicinal product contains soya-bean oil, which may rarely cause severe allergic reactions. Cross allergic reactions has been observed between soya-bean and peanut.

### 3. How to use StructoKabiven Perifer

Your doctor will decide on the dose for you individually depending on your body weight and function. StructoKabiven Perifer will be given to you by a health professional. You will receive your medicine by infusion into a peripheral or a central vein. You may be monitored during your treatment.

**If you receive more StructoKabiven Perifer than you should**
It is very unlikely that you will receive more infusion than you should as your doctor or nurse will monitor you during the treatment.
The effects of an overdose may include nausea, fever, vomiting, shivering, sweating and fluid retention. Hyperglycaemia (too much sugar in your blood) and electrolyte disturbances have also been reported. In case of overdose there is a risk of taking in too much fat. This is called ‘fat overload syndrome’. See section 4 “Possible side effects” for more information.
If you experience any of the symptoms described above or believe that you have received too much StructoKabiven Perifer inform your doctor or nurse immediately. The infusion may either be stopped immediately or continued with a reduced dosage. These symptoms will usually disappear on reducing the rate or stopping the infusion.

If you have any further questions on the use of this product, ask your doctor or nurse.

4. Possible side effects

Like all medicines, StructoKabiven Perifer can cause side effects, although not everybody gets them.

If during the infusion you get fever, rash, swelling of tongue or throat, difficulty in breathing, chills, sweating, nausea or vomiting, tell the health care professional immediately. These symptoms might be caused by an allergic reaction to the medicine.

**Uncommon** (affects 1 to 10 users in 1000): high blood (plasma) levels of compounds from the liver, nausea, headache, rise in body temperature.

**Rare** (affects 1 to 10 users in 10000): fast heart beat (tachycardia), high blood pressure

**Very rare** (affects less than 1 user in 10000): difficulty in breathing, diarrhoea, rash, back pain, dizziness

**Fat overload syndrome**

This might happen when your body has problems using fat, because of having too much StructoKabiven Perifer. It may also happen because of a sudden change in your condition (such as kidney problems or infection). Possible symptoms are fever, increased levels of fat in your blood, your cells and your tissues, disorders in various organs and coma. All these symptoms will usually disappear if the infusion is discontinued.

**Excess of amino acids**

This might happen when the amino acid level is exceeded when the infusion rate is increased. Possible symptoms are nausea, vomiting, shivering, sweating and a rise in your body temperature. If you have kidney problems your doctor may want to perform blood tests to measure the amount of nitrogen containing substances in your blood.

**Excess glucose**

This may occur when your body has problems removing glucose from your body as this will result in too much sugar in your blood (hyperglycaemia).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store StructoKabiven Perifer

- Keep out of the reach and sight of children.

- Do not store above 25°C.
• Do not freeze.

• Keep the container in the overpouch

• Do not use StructoKabiven Perifer after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

• Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What StructoKabiven Perifer contains

<table>
<thead>
<tr>
<th></th>
<th>1206 ml</th>
<th>1904 ml</th>
<th>Per 1000 ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amino acid solution with electrolytes</td>
<td>380 ml</td>
<td>600 ml</td>
<td>315 ml</td>
</tr>
<tr>
<td>Glucose 13%</td>
<td>656 ml</td>
<td>1036 ml</td>
<td>544 ml</td>
</tr>
<tr>
<td>Fat emulsion</td>
<td>170 ml</td>
<td>268 ml</td>
<td>141 ml</td>
</tr>
</tbody>
</table>

This corresponds to the following total compositions:

**Active ingredients**

<table>
<thead>
<tr>
<th></th>
<th>1206 ml</th>
<th>1904 ml</th>
<th>Per 1000 ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purified structured triglyceride</td>
<td>34 g</td>
<td>54 g</td>
<td>28 g</td>
</tr>
<tr>
<td>Glucose (as monohydrate)</td>
<td>85 g</td>
<td>135 g</td>
<td>71 g</td>
</tr>
<tr>
<td>Alanine</td>
<td>5.3 g</td>
<td>8.4 g</td>
<td>4.4 g</td>
</tr>
<tr>
<td>Arginine</td>
<td>4.6 g</td>
<td>7.2 g</td>
<td>3.8 g</td>
</tr>
<tr>
<td>Glycine</td>
<td>4.2 g</td>
<td>6.6 g</td>
<td>3.5 g</td>
</tr>
<tr>
<td>Histidine</td>
<td>1.1 g</td>
<td>1.8 g</td>
<td>0.93 g</td>
</tr>
<tr>
<td>Isoleucine</td>
<td>1.9 g</td>
<td>3.0 g</td>
<td>1.6 g</td>
</tr>
<tr>
<td>Leucine</td>
<td>2.8 g</td>
<td>4.4 g</td>
<td>2.3 g</td>
</tr>
<tr>
<td>Lysine (as acetate)</td>
<td>2.5 g</td>
<td>4.0 g</td>
<td>2.1 g</td>
</tr>
<tr>
<td>Methionine</td>
<td>1.6 g</td>
<td>2.6 g</td>
<td>1.3 g</td>
</tr>
<tr>
<td>Phenylalanine</td>
<td>1.9 g</td>
<td>3.1 g</td>
<td>1.6 g</td>
</tr>
<tr>
<td>Proline</td>
<td>4.2 g</td>
<td>6.7 g</td>
<td>3.5 g</td>
</tr>
<tr>
<td>Serine</td>
<td>2.5 g</td>
<td>3.9 g</td>
<td>2.1 g</td>
</tr>
<tr>
<td>Taurine</td>
<td>0.38 g</td>
<td>0.60 g</td>
<td>0.32 g</td>
</tr>
<tr>
<td>Threonine</td>
<td>1.7 g</td>
<td>2.6 g</td>
<td>1.4 g</td>
</tr>
<tr>
<td>Tryptophan</td>
<td>0.76 g</td>
<td>1.2 g</td>
<td>0.63 g</td>
</tr>
<tr>
<td>Tyrosine</td>
<td>0.15 g</td>
<td>0.24 g</td>
<td>0.12 g</td>
</tr>
<tr>
<td>Valine</td>
<td>2.4 g</td>
<td>3.7 g</td>
<td>2.0 g</td>
</tr>
<tr>
<td>Calcium chloride (as calcium chloride dihydrate)</td>
<td>0.21 g</td>
<td>0.34 g</td>
<td>0.18 g</td>
</tr>
<tr>
<td>Sodium glycerophosphate (as hydrate)</td>
<td>1.6 g</td>
<td>2.5 g</td>
<td>1.3 g</td>
</tr>
<tr>
<td>Magnesium sulphate (as magnesium sulphate heptahydrate)</td>
<td>0.46 g</td>
<td>0.72 g</td>
<td>0.38 g</td>
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<tr>
<td>Potassium chloride</td>
<td>1.7 g</td>
<td>2.7 g</td>
<td>1.4 g</td>
</tr>
<tr>
<td>Sodium acetate (as sodium acetate trihydrate)</td>
<td>1.3 g</td>
<td>2.0 g</td>
<td>1.1 g</td>
</tr>
<tr>
<td>Zinc sulphate (as zinc sulphate heptahydrate)</td>
<td>0.005 g</td>
<td>0.008 g</td>
<td>0.004 g</td>
</tr>
</tbody>
</table>
The other ingredients are: glycerol, purified egg phospholipids, sodium hydroxide (pH-adjustment), acetic acid glacial (pH-adjustment) and water for injections.

**What StructoKabiven Perifer looks like and contents of the pack**
Glucose- and aminoacid solutions are clear, colourless or slightly yellow and free from particles. The fat emulsion is white and homogenous.

*Pack sizes:*
1 x 1206 ml, 4 x 1206 ml
1 x 1904 ml, 3 x 1904 ml (Excel), 4 x 1904 (Biofine)

Not all pack sizes may be marketed

**Marketing Authorisation Holder and Manufacturer**
Marketing authorisation holder:
To be completed nationally

Manufacturer:
Fresenius Kabi AB, 751 74 Uppsala, Sweden
Fresenius Kabi GmbH, Graz, Austria

**This medicinal product is authorised in the Member States of the EEA under the following names:**

<table>
<thead>
<tr>
<th>Country</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>StructoKabiven Perifer</td>
</tr>
<tr>
<td>Belgium</td>
<td>StructoKabiven Perifeer</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>StructoKabiven Peripheral</td>
</tr>
<tr>
<td>Denmark</td>
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<tr>
<td>Finland</td>
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<td>Germany</td>
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<tr>
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<tr>
<td>Sweden</td>
<td>StructoKabiven Perifer</td>
</tr>
</tbody>
</table>

**This leaflet was last approved in** 2009-06-24.

The following information is intended for medical or healthcare professionals only:

**Warnings and precautions for use**
To avoid risks associated with too rapid infusion rates, it is recommended to use a continuous and well-controlled infusion, if possible by using a volumetric pump.

Since an increased risk of infection is associated with the use of any central vein, strict aseptic precautions should be taken to avoid any contamination during catheter insertion and manipulation.

Serum glucose, electrolytes and osmolarity as well as fluid balance, acid-base status and liver enzyme tests should be monitored.

Any sign or symptom of anaphylactic reaction (such as fever, shivering, rash or dyspnoea) should lead to immediate interruption of the infusion.

StructoKabiven Perifer should not be given simultaneously with blood in the same infusion set due to the risk of pseudoagglutination.

Thrombophlebitis may occur if peripheral veins are used for infusion. The catheter insertion site should be evaluated daily for local signs of thrombophlebitis.

**Method of administration**

Intravenous use, infusion into a peripheral or a central vein.

To provide total parenteral nutrition, trace elements and vitamins should be added to StructoKabiven Perifer according to the patients need.

**Infusion rate**

The maximum infusion rate for glucose is 0.25 g/kg/h, for amino acid 0.1 g/kg/h, and for fat 0.15 g/kg/h.

The infusion rate should not exceed 3.0 ml/kg/hour (corresponding to 0.21 g glucose, 0.10 g amino acid, and 0.08 g fat/kg/hour). The recommended infusion period is 14-24 hours.

**Precautions for disposal**

Do not use if package is damaged. Use only if the amino acid and glucose solutions are clear and colourless or slightly yellow and the fat emulsion is white and homogenous. The contents of the three separate chambers have to be mixed before use and before any additions are made via the additive port.

After separation of the peelable seals the bag should be inverted on a number of occasions to ensure a homogenous mixture which does not show any evidence of phase separation.

For single use only. Any mixture remaining after infusion must be discarded.

**Compatibility**

Only medicinal or nutrition solutions for which compatibility has been documented may be added to StructoKabiven Perifer. Compatibility for different additives and the storage time of the different admixtures will be available upon request.

Addition should be made aseptically.

**Shelf-life after mixing**

Chemical and physical in-use stability of the mixed three chamber bag has been demonstrated for 36 hours at 25°C. From a microbiological point of view the product should be used immediately. If not used
immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2-8°C.

*Shelf-life after mixing with additives*
From a microbiological point of view, the product should be used immediately when additions have been made. If not used immediately, the in-use storage time and conditions prior to use are the responsibility of the user and should normally not be longer than 24 hours at 2-8°C.
**StructoKabiven Perifer Instructions for use**

**The bag**

1. Notches in the overpouch
2. Handle
3. Hole for hanging the bag
4. Peelable seals
5. Blind port (only used during Manufacturing)
6. Additive port
7. Infusion port
8. Oxygen absorber

**1. Removal of overpouch**

- To remove overpouch, hold the bag horizontally and tear from the notch close to the ports along the upper edge (A).
- Then simply tear the long side, pull off the overpouch and discard it along with the oxygen absorber (B).
2. Mixing

- Place the bag on a flat surface.
- Roll up the bag tightly from the handle side towards the ports, firstly with the right hand and then applying a constant pressure with the left hand until the vertical seals are broken. The vertical peel seals open due to the pressure of the fluid. The peel seals can also be opened before removing the overpouch.

Please note: The horizontal seal should not be broken. The liquids mix easily although the horizontal seal remains closed.

- Mix the contents of the three chambers by inverting the bag three times until the components are thoroughly mixed.
3. Finalising the preparation:

- Place the bag on a flat surface again. Shortly before injecting the additives, break off the tamper-evident arrow flag from the white additive port (A).

**Please note:** The membrane in the additive port is sterile.

- Hold the base of the additive port. Insert the needle, inject the additives (with known compatibility) through the centre of the injection site (B).
- Mix thoroughly between each addition by inverting the bag three times. Use syringes with needles of 18-23 gauge and a length of max. 40 mm.

- Shortly before inserting the infusion set, break off the tamper evident arrow flag from the blue infusion port (A).

**Please note:** The membrane in the infusion port is sterile.

- Use a non-vented infusion set or close the air-inlet on a vented set.
- Hold the base of the infusion port.
- Push the spike through the infusion port. The spike should be fully inserted to secure it in place.

**Please note:** The inner part of the infusion port is sterile.

4. Hooking up the bag

- Hook the bag up by the hole below the handle.